510(k) Summary of Safety and Effectiveness Information

K061898

Regulatory Authority:	**Safe Medical Devices Act of 1990, 21 CFR 807.92**
Company:	**BioLase Technology, Inc. 4 Cromwell Irvine, CA 92618**

JAN 26 2007

Contact:	**Ms. Ioana M. Rizoiu BioLase Technology, Inc. 4 Cromwell Irvine, CA 92618 Tel: (949) 226 8144 Fax: (949) 273 6680**
Trade Name:	***EZLase*™**
Common Name:	**Dental diode laser**
Classification Name:	**Surgical laser instrument**
Classification Code:	**79 GEX**

Equivalent Devices:

BioLase Technology, Inc.	**LaserSmile™**
Hoya ConBio, Inc.	**LVI lase**
Hoya ConBio, Inc.	**DioDent II**

Device Description:

The ***EZLase*™** dental diode laser system may be used to perform various soft tissue dental applications. The system uses advanced laser technology to incise, excise, vaporize, coagulate and ablate intra-oral soft tissues. A Gallium Aluminum Arsenide (GaAlAs) and/or an Indium Gallium Arsenide Phosphorous solid-state laser diode emit infrared laser energy to the various oral soft tissues targeted during procedure. This energy is transmitted via a flexible fiberoptic cable to the handpiece that emits the energy to the targeted tissue site. A visible light is emitted at the same time to visually pinpoint the treatment location. The power output and pulse width may be adjusted to specific user requirements.

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Indications for Use:

Dental Soft Tissue Indications for:

Incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

Excisional and incisional biopsies
Exposure of unerupted teeth
Fibroma removal
Frenectomy
Frenotomy
Gingival troughing for crown impressions
Gingivectomy
Gingivoplasty
Gingival incision and excision
Hemostasis and coagulation
Implant recovery
Incision and drainage of abscess
Leukoplakia
Operculectomy
Oral papillectomies
Pulpotomy
Pulpotomy as an adjunct to root canal therapy
Reduction of gingival hypertrophy
Soft tissue crown lengthening
Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa.
Vestibuloplasty

Laser Periodontal procedures, including:

Laser soft tissue curettage
Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)

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Contraindications:

6.6.1 All clinical procedures performed with ***EZLase***™ must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, sleep apnea, an immune system deficiency and other such conditions. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

Substantial Equivalence:

There are no unique applications, indications, materials or specifications presented herein. All the submitted indications for use retain the same meaning as their equivalent indications cleared by the FDA in the following 510k clearances: K030539 for ***LaserSmile***™, K041721 for ***LVI Lase*** and K050274 for ***DioDent II***.

Conclusion:

EZLase™ is substantially equivalent to dental products previously cleared for marketing. ***EZLase***™ performs the same indications for use through the same mechanism as the other cleared devices. Evidence of equivalence has been demonstrated through the following:

- Equivalent performance specification
- Equivalent intended use
- Feature comparison table

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biolase Technology Inc.
% Ms. Ioana M. Rizoiu
VP, Clinical Research
and Development
4 Cromwell
Irvine, California 92618

JAN 26 2007

Re: K061898
Trade/Device Name: *EZLase*™
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 19, 2006
Received: December 20, 2006

Dear Ms. Rizoiu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K061898

Device Name: *EZLase*™

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Frenotomy
Gingival troughing for crown impressions
Gingivectomy
Gingivoplasty
Gingival incision and excision
Hemostasis and coagulation
Implant recovery
Incision and drainage of abscess
Leukoplakia
Operculectomy
Oral papillectomies
Pulpotomy
Pulpotomy as an adjunct to root canal therapy
Reduction of gingival hypertrophy
Soft tissue crown lengthening
Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa.
Vestibuloplasty

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Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter-Use _____
(Per 21 CFR 801.109)

MXM

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(K) Number K061898